EXHIBIT C

Atty. Docket No. 24222-X3

Certificate of Mailing/Transmission (37 C.F.R. § 1.8(a)):

[X] Pursuant to 37 C.F.R. § 1.8, I hereby certify that this paper and all enclosures are being deposited with the United States Postal Service as first class mail on the date indicated below in an envelope addressed to the Commissioner for Patents, Washington D.C. 20231.

3/29/2006 Name of Person Certifying: Judy Anderson
Printed Name: Judy Anderson

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	CHERUKURI, S. Rao	Attorney Docket:	24222-X3
Filing Date:	10/19/2001	Examiner:	Fubara, B.
Serial No.:	09/982,093	Group Art Unit:	1615
Title:	Drug Delivery Systems		

Commissioner for Patents
Washington, D.C. 20231

DECLARATION OF S. Rao CHERUKURI UNDER 37 C.F.R. § 1.132

I, S. Rao CHERUKURI, citizen of United States of America, hereby declare that:

1. I have a Bachelor of Pharmacy and a Master of Pharmacy degrees, both from Andhra University, India, and an MBA from University of Pennsylvania, Wharton School of Management. My career in the United States started in 1973 as R&D Manager with Philadelphia Chewing Gums Corporation, Haverton, PA. From 1978 to 1981, I worked as Senior Research Manager, R&D at E.R. Squibb/Life Savers Corporation. In 1981 I joined Warner Lambert & Company and was their Director of Worldwide Technology Development when I left in 1991. I joined Fuisz International, Chantilly, VA in 1992 as Senior Director of Technology and held several progressively senior research and management positions and became President, Consumer Healthcare division. I left Fuisz in 2000, and founded Capricorn Pharma Inc., in Frederick, MD to develop innovative technologies in pharmaceutical, confectionary and neutraceutical businesses. My curriculum vitae is set forth in Appendix A to this Declaration. Over the years, from 1978 till to-date, my work (as a sole inventor or as a co-inventor) resulted in issuance of about one hundred United States patents and several international counterparts. Please see

Appendix B for a list of my issued U.S. patents. In view of the above, I believe that I am one of skill in the art in the subject matter of the above-identified application.

2. I have read the subject application papers and the Office Action issued February 2, 2005. I am aware of the issues raised by the Patent Office in the previous and pending Office Actions, and in particular the reference of record, U.S. Patent 6,197,828 issued to Jerussi, et al (hereinafter, "Jerussi Patent").

3. All experiments disclosed in this Declaration were designed and supervised by me and were conducted by Mr. Revanth Babu Mutyala while acting under my constant guidance and supervision. Mr. Mutyala has been employed since June 2004 as a Pharmaceutical Scientist in the Research & Development department at Capricorn Pharma.

4. The experiments as disclosed in the present Declaration were conducted to compare the caplets of about 1mm to about 7 mm as disclosed and claimed in the above-referenced pending application with the relevant product(s) of Jerussi's Patent. The comparison would include desirable attribute, including the claimed element, namely, dissolution profile.

5. Using the Jerussi Patent as guide, I attempted to prepare oral formulations as described in Example 7, column 26, line 28 through column 27, line 22. Example 7 discloses two oral formulations, one a hard gelatin capsule dosage form and the other a compressed tablet dosage form. The hard gelatin dosage form is simply a capsule filled with blended powder of the active drug and is not expected to provide any controlled or extended release properties. Therefore, this dosage form cannot serve as a comparative product for present purposes. Accordingly, this dosage form was not prepared or used in comparing with a product of the subject invention.

6. Subsequent to the capsule formulation, Jerussi Patent disclosed a compressed tablet dosage form. There were three strengths disclosed with their composition in TABLE III. I attempted to follow the exact procedure as outlined in column 27, lines 16-20. For illustration purposes, I attempted to use the example of 100mg of the active drug, in our

case being Venlafaxine HCl. The details of this experiment are set out in the following paragraphs 7-12.

7. EXPERIMENT 1: Microcrystalline cellulose (90mg), pregelatanized starch (82.80mg) and Croscarmellose sodium (7.0mg) were mixed together in a double cone blender. The active ingredient Venlafaxine HCl (100mg) was blended with the mixture of excipients until a uniform blend was formed. The texture was a fine granular powder.

8. The dry blend was screened through an ASTM mesh#20 and was blended with magnesium stearate (0.2mg) which was previously sifted through ASTM mesh#40.

9. I attempted to compress the resulting powder blend using Pilot Tablet press with 10 Stations. This equipment is expected to produce a tablet of 9mm size. However, the powder blend was not compressible into a tablet, i.e., remained as a powder.

10. EXPERIMENT 2: In order to improve compressibility of the composition, I attempted to granulate the product, even though granulation was not suggested in the Jarussi Patent Example 7.

11. Using the procedures described above in paragraph 7, dry blended fine powder was obtained. Separately, a 5% w/v concentrated solution of Plasdone K-29/32 (Povidone) (8.40mg) was prepared in a glass beaker in isopropyl alcohol 99% USP. The dry blend was wet granulated with povidone solution.

12. The wet granulated material was dried in a Thelco lab dryer. The dried material was sifted on a ASTM mesh# 18 and was blended with magnesium stearate (0.2mg) lubricant, which was previously sifted through ASTM mesh#40.

13. I attempted to compress the material on a pilot tablet press of 10 stations and was operated at 12 rpm. This equipment is expected to produce a tablet of 9mm size. However, the powder blend was not compressible into a tablet, i.e., remained as a powder.

14. EXPERIMENT 3: In order to improve compressibility and provide hardness to the tablets to be formed, Experiment 2 above was repeated with a slight modification. The procedure described in Paragraph 11 was followed exactly as before, but in paragraph 12, the modification entailed adding talc (4.92mg) to the magnesium stearate blend.

15. I attempted to compress the material on a pilot tablet press of 10 stations and was operated at 12 rpm. This equipment is expected to produce a tablet of 9mm size. The material had satisfactory compressibility, but the tablets did not have sufficient hardness and the tablets are sticking to the punches. Therefore, this product was not of pharmaceutical quality and thus could not be used for comparative dissolution purposes.

16. EXPERIMENT 4: To improve tablet hardness and minimize or eliminate tablet stickiness, Experiment 3 was modified further. The modification entailed adding a higher amount of talc (16.43mg) to the magnesium stearate blend. With this modification, I was able to produce 9mm tablets of acceptable hardness and compressibility.

17. The product was subject to dissolution conditions. Sampling points were:- 1, 2, 4, 6, 10, 12, 18, 24 hrs. For each test, 37.5mg/75mg/150mg of venlafaxine was used. 8mL samples were withdrawn at predetermined times using an automated sampler. The venlafaxine concentration in each sample was determined using an HPLC using the method described under the Assay for all dissolution media. The percentage of venlafaxine released over time was calculated and plotted as an average of 6 runs using calibration curves consistent with Beer's law.

18. The assay conditions were as following: Column: Zorbax Eclipse XDB-C_8, 5µm, 4.6 x 150mm; Mobile phase: Aqueous 0.02M NaH_2PO_4 : H_3PO_4(ml) : Acetonitrile :1-Heptanesulfonic acid, Sodium salt (700:0.6:300:5mM); flow rate: 1.0 ml/min; column temperature: 25C; injection volume : 10 uL; UV detection: 226 nm; run time: 8 minutes. The data are presented in graphical form in Appendix C.

19. EXPERIMENT A: Venlafaxine mini-tablets were prepared by essentially following the methods disclosed in the subject application. The mini-tablets were subject to dissolution conditions. The data are presented in graphical form in Appendix C.

20. As can be seen by comparing the dissolutions in Appendix C, venlafaxine mini-tablets of the subject application having the size of 3mm have provided a controlled release of the active over a time span of about 24 hrs. In contrast, the venlafaxine tablets of 9mm size made according to the Jarussi Patent disclosure provided a quick release of the active and thus are not suitable for controlled release applications.

21. I further declare that all statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 21st July 2005

S. Rao CHERUKURI